A Thesis
Entitled
The Immediate Effects of Electromyographic Biofeedback on Corticomotor Excitability of the Quadriceps in Healthy Individuals
By
David Florea II, ATC
Submitted to the Graduate Faculty as partial fulfillment of the requirements for the Master of Science Degree in Exercise Science

Dr. Brian Pietrosimone, Committee Chair
Dr. Phillip Gribble, Committee Member
Dr. Michael Tevald, Committee Member
Dr. Patricia Komuniecki, Dean
College of Graduate Studies

The University of Toledo
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An Abstract of

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Objective: The objective of this study was to determine the immediate effects of a single bout of electromyographic biofeedback on corticomotor excitability in healthy individuals. Design: A cross-over study with a one-week period between each testing session was conducted in a laboratory setting. Participants: Twelve participants (6 male, 6 female; 21.41 ± 4.41 years; 172.82 ± 11.23 cm; 72.58 ± 15.77 kg). Procedure: Participants were position in the Biodex System 2 dynamometer to measure maximal voluntary force to establish a baseline MVIC value for each testing session. Submaximal contractions at five percent of this maximal contraction were used to standardize voluntary contraction during corticomotor testing. A Magstim Rapid was used to administer transcranial magnetic stimulation to the motor cortex to measure corticomotor excitability. Active motor threshold (AMT) was established as the lowest intensity required to elicit a motor evoked potential (MEP) of ≥100μV amplitude in at least 5 of 10 trials. Five MEPs were collected at AMT. The participants then performed a MVIC of the quadriceps. When maximal effort plateaued a stimulus was given and the MEP peak-to-peak amplitude was recorded for analysis. This was performed for 5 consecutive trials.
with 60 seconds of rest between each MVIC. During the electromyographic biofeedback (EMG-BF) testing session a Myotrac Infiniti handheld biofeedback unit was used to monitor electrical activity of the vastus lateralis. A target line was established on the biofeedback unit at 110% of their peak EMG values. Participants performed a MVIC while using EMG-BF. When maximal effort plateaued, magnetic stimulus was produced over the motor cortex and the quadriceps MEP peak-to-peak amplitude was recorded for analysis. This was performed for 5 consecutive trials with 60 seconds of rest between each MVIC. Maximum muscle response (M_{max}) was recorded and used to normalize MEP. **Statistics:** Significance determined using dependent t-tests between the changes in MEP amplitude during the control and EMG-BF sessions (p< 0.05). Cohen’s $d$ effect sizes with corresponding 95% confidence intervals were calculated. **Results:** The percent change scores for MEP amplitude at AMT were significantly greater in the biofeedback condition compared to the control ($t_{11} = -2.308, p= .041$). Large effect sizes were found for both the control ($d= 3.92, 95\% \text{ CI} = 2.45-5.12$), and biofeedback condition, ($d= 2.77, 95\% \text{ CI} =1.58- 3.78$). A moderate effect size was found between the two conditions, ($d= 0.62, 95\% \text{ CI}= -0.22- 1.42$). **Conclusion:** The results from this study suggest that a single bout of EMG-BF can be used to increase corticomotor excitability in healthy individuals.
# Table of Contents

Abstract ........................................................................................................................................... iii

Table of Contents .......................................................................................................................... v

List of Tables .................................................................................................................................. viii

List of Figures ............................................................................................................................... ix

1 Chapter 1

1.1 Introduction ............................................................................................................................ 1

1.2 Statement of Purpose .............................................................................................................. 2

1.3 Dependent Variables .............................................................................................................. 3

1.4 Independent Variables ........................................................................................................... 3

1.5 Research Question .................................................................................................................. 3

1.6 Null Hypothesis ..................................................................................................................... 3

1.7 Research Hypothesis .............................................................................................................. 4

1.8 Specific Aims .......................................................................................................................... 4

1.9 Operational Definitions ....................................................................................................... 4

1.10 Potential Limitations .......................................................................................................... 5

1.11 Significance ......................................................................................................................... 5

2 Chapter 2- Literature Review

2.1 Introduction ........................................................................................................................... 7
2.2 Arthrogenic Muscle Inhibition ................................................................. 7
2.3 Disinhibitory Modalities ................................................................. 8
   2.3.1 Cryotherapy in the Reduction of AMI ................................................. 9
   2.3.2 TENS in the Reduction of AMI ...................................................... 10
2.4 Electromyographic Biofeedback ....................................................... 11
   2.4.1 EMG-BF in the Reduction of AM ................................................. 12
2.5 Transcranial Magnetic Stimulation .................................................... 12
2.6 Hoffman Reflex ............................................................................. 13

3 Chapter 3 – Methods

3.1 Experimental Design ........................................................................ 15
3.2 Subjects ............................................................................................ 16
3.3 Instrumentation ................................................................................ 17
3.4 Procedures ......................................................................................... 19
   3.4.1 Intervention ............................................................................... 22
3.5 Statistical Analysis .......................................................................... 23

4 Chapter 4- Results

4.1 Results ............................................................................................. 24

5 Chapter 5- Discussion ........................................................................ 28

References .......................................................................................... 35
Appendix

A- University of Toledo IRB Consent Form ................................................................. 39

B- Knee Injury History Form .................................................................................... 46
List of Tables

Table 4.1.1  Participant Demographics ..............................................................................25
Table 4.1.2  Significance and Effect Size ..........................................................................25
Table 4.1.3  Average Torque Table ...................................................................................26
List of Figures

3-1 Procedure Timeline........................................................................................................16
4-1 Motor Evoked Potential Change Scores.........................................................................26
4-2 Average Torque Value..................................................................................................27
4-3 Effect Size................................................................................................................27
Chapter I

1.1 Introduction

Neuromuscular alterations are common following lower extremity injury. These alterations may present as an inhibition of the musculature surrounding a joint. Neural alterations contribute to atrophy, strength deficiencies (1), and altered activation levels (2) in muscles of the affected joint. Neuromuscular deficits following knee injury can stem from either spinal reflex or corticomotor pathways. Altered control of the quadriceps has been documented following knee injury. (3) Changes in corticomotor excitability are also associated with an increase in afferent activity at the joint. (1) This afferent activity can be altered by swelling or inflammation after joint injury. (1, 4) The interruption of the delivery of information to the spinal cord is an influencing factor in muscular inhibition. Interventions such as cryotherapy (5, 6), and transcutaneous electrical nerve stimulation (TENS) (7) have been used in an effort to reduce muscular inhibition by impacting the spinal reflex pathway. Currently there are no interventions being researched that may reduce muscular inhibition by targeting corticomotor pathways.

Electromyographic biofeedback (EMG-BF) is often used along with conventional rehabilitation techniques in order to increase strength (8, 9), and neuromuscular control. Literature suggests that when used in combination with traditional strength training
protocol the EMG-BF supplementation provides greater outcomes than with strength training alone. (9, 10) EMG-BF has been shown to help restore quadriceps strength, (10-12) improve the activation of quadriceps (13) and muscle fiber recruitment in patients following minor arthroscopic (14) surgeries and those with patellofemoral pain syndrome.

Arthrogenic muscle inhibition (AMI) is a limiting factor in rehabilitation following joint injury. AMI negatively affects neural pathways by altering the afferent information that is being transmitted to the central nervous system and decreasing the excitability of motor neuron pool of the quadriceps. (15) Healthcare professionals should be aware of neuromuscular inhibition, and rehabilitation protocol should incorporate the use of interventions aimed at the reduction of AMI. However, there is a little evidence to show which intervention is the most effective in addressing the neuromuscular complications. The most common methods being researched aimed at reducing AMI in the quadriceps muscle group, are cryotherapy (6) and transcutaneous (7) nerve stimulation. EMG- biofeedback (EMG-BF) is a useful rehabilitation tool used in rehabilitation for arthroscopic knee surgeries (9, 12, 16), patellofemoral pain syndrome (5, 10), and knee osteoarthritis (17). EMG-BF is used to help patients gain neuromuscular control and reeducation of the muscle. Current research suggests that when traditional exercises are supplemented with the use of EMG-B the benefits are greater than with exercise alone. (8, 10) However it is unclear how EMG-BF may affect corticomotor pathways.

1.2 Statement of the Purpose
The purpose of this investigation is to determine the acute effects during a single bout of EMG- BF on corticomotor excitability, in healthy individuals, when compared to those who not receive biofeedback.

1.3 Dependent Variables

1) Corticomotor Excitability as measured by Transcranial Magnetic Stimulation
   - Changes in Motor Evoked Potentials at Active Motor Threshold for the vastus lateralis
2) Torque during a maximal voluntary isometric contraction of the quadriceps
   - Changes in MVIC during corticomotor excitability testing between the control and EMG-BF intervention session

1.4 Independent Variables

1) Condition
   - Intervention = Participants being supplemented with electromyographic biofeedback during maximal voluntary isometric contraction of the quadriceps during corticomotor excitability testing
   - Control = Participants performing maximal voluntary isometric contraction of the quadriceps during corticomotor excitability testing

1.5 Research Question
Does the supplementation of electromyographic biofeedback result in an increase in corticomotor excitability in healthy individuals?

1.6 Null Hypothesis

During the supplementation of electromyographic biofeedback during a maximal voluntary isometric contraction there will be NO significant increases in corticomotor excitability.

1.7 Research Hypothesis

1. During the supplementation of electromyographic biofeedback during a maximal voluntary isometric contraction there WILL BE significant increases in Motor Evoked Potential Amplitude.

2. There WILL BE NO significant increases in torque between the control and intervention testing sessions.

1.8 Specific Aims

The Research Hypothesis will be tested through the examination of two specific aims:

1. To examine the immediate effects of electromyographic biofeedback on corticomotor excitability
   a. This aim was accomplished by testing the corticomotor involvement using transcranial magnetic stimulation

2. To monitor peak torque during each corticomotor excitability testing session
a. This aim was accomplished by monitoring torque using the Biodex System 2 Dynamometer in conjunction with Biopac AcqKnowledge software

1.9 Operational Definitions

- Electromyographic Biofeedback- Modality that visualizes electrical activity of the muscle. Often used as tool to regain voluntary muscular control.
- AMI – Arthrogenic Muscle Inhibition
  Ongoing inhibition of musculature surrounding a joint due to injury or distention of joint; due to afferent activity disruption caused by injury
- Maximal Voluntary Isometric Contraction- Used as a measurement of peak strength of a muscle
- TMS – Transcranial magnetic stimulation. Testing method used to establish corticomotor contributions to neuromuscular activity.
- MEP – Motor evoked potential. Electromyographical representation used to quantify the corticomotor contributions to neuromuscular activity during TMS testing.

1.10 Potential Limitations

There is no previous literature that demonstrates the ability of EMG-BF to alter corticomotor excitability. Another possible limitation includes sample size. However this
is unlikely because we are utilizing healthy individuals in this study. A greater number of participants could further support the claims that EMG-BF can be used to increase corticomotor excitability.

1.11 Significance

Knee injury is prevalent in the active population and resultant disability may stem from neuromuscular alterations such as decreased activation and weakness.\(^\text{(2, 15, 18, 19)}\) Without clinical management this may progress to chronic disability and joint degeneration such as osteoarthritis (19-21). There is a need to identify the most influential intervention that may excite neural pathways and reduce inhibition.\(^\text{(5)}\) Reducing inhibition early in the rehabilitation protocol may allow for greater gains in strength, and activation due to an increase in motor neuron recruitment. Previous research has shown that transcutaneous nerve stimulation (TENS)\(^\text{(7)}\) and cryotherapy\(^\text{(5, 6)}\) are effective in the reduction of AMI. Both cryotherapy and TENS target the increase of motor excitability by addressing the alterations through the spinal pathway. EMG-BF targets motor excitability by addressing the deficits that originate from the corticomotor pathway. EMG-biofeedback is used to help regain voluntary neuromuscular control, when combined with traditional strength training exercises has demonstrated improvement in activation of musculature. Increase in activation is often credited to the real time feedback, which allowed for integration of sensory and motor recruitment of muscles.\(^\text{(5)}\) However, the immediate effects of EMG-BF on corticomotor excitability are unknown. This study will aim to determine the mechanism of EMG-BF and its immediate effects on corticomotor excitability.
Chapter 2

Literature Review

2.1 Introduction
The purpose of this literature review is to evaluate the use of electromyographic (EMG) biofeedback and its immediate effects on neuromuscular function of the quadriceps muscle group as measured by corticomotor excitability. EMG biofeedback has been noted to be effective by increasing peak torque, (12, 16) muscular activation (5), and range of motion (9, 22) during rehabilitation of patellofemoral pain syndrome (5, 13), knee osteoarthritis, (17), and arthroscopic knee surgeries. (9, 14) Knee injury is prevalent in the active population and resultant disability may stem from neuromuscular alterations such as decreased activation and weakness. (2, 15, 18, 19) Without effective clinical management this may progress to chronic disability and joint degeneration such as osteoarthritis. (19-21)

2.2 Arthrogenic Muscle Inhibition

Arthrogenic muscle inhibition (AMI) is a limiting factor in rehabilitation, and contributes to atrophy and strength deficiencies of surrounding muscles of the affected joint. (1, 4) AMI is characterized by the inability for the muscle to contract even when it is
not injured. (2, 4) It is normally referred to as a reflex injury because it cannot be controlled voluntarily. (2) AMI may prevent maximal voluntary contraction of the quadriceps, therefore, quadriceps strength gains observed with traditional exercises may not be optimized in the presence of AMI. (19) This is suggested to be the body’s natural defense mechanism following musculoskeletal injury by discouraging use and preventing potentially harmful movements. (2, 19) Medical professionals responsible for implementing rehabilitation plans should be aware of AMI and incorporate the use of interventions that target AMI. (2) The patient and clinician may notice gains in strength, but without addressing AMI the musculature may develop perpetual inhibition or the inability to overcome AMI. (5, 6) However, which interventions are most effective at targeting neuromuscular dysfunction remains relatively unknown. Many studies (8-10) have theorized on the various therapeutic interventions by which AMI can be reduced including: aspiration, corticosteroid injection, NSAIDS, local anesthetic, cryotherapy, transcutaneous electric nerve stimulation (TENS), and neuromuscular electrical stimulation (NMES). (1) The most common methods currently being researched to reduce AMI in the quadriceps muscle group are cryotherapy, (1, 4, 6, 7, 23-25) and TENS. (5, 25, 26)

2.3 Disinhibitory Modalities

Since AMI may be a limiting factor in rehabilitation, studies have investigated interventions aimed at limiting the effects of AMI in the quadriceps after knee injury. Therapeutic strengthening exercises are used to counteract muscle atrophy. (2, 5, 21) However, strengthening programs often neglect the neuromuscular consequences of the
surgical intervention. Returning a patient to normal activities or competitive sports without addressing the neuromuscular deficit and weakness may result in increased susceptibility to fatigue altered gait patterns and increased risk of reinjury. (5, 27)

Reduction of AMI is crucial in the rehabilitation process. It is suggested that disinhibitory methods may be more effective if AMI is addressed before beginning active strengthening exercises. (25) Reducing inhibition early on may allow for greater strength gains and improved functional movement patterns due to more effective motor recruitment. (5, 25) Current research has shown that cryotherapy and TENS can be effective methods of reducing AMI. (1, 19, 24, 25)

2.3.1 Cryotherapy in the Reduction of AMI

Cryotherapy decreases the temperature of the nerve; because of this, nerve conduction velocity is reduced along with muscle spasm and general pain responses associated with injury. (25) Previous studies (5, 6, 25) have looked at the effect of joint cooling on the central activation ratio (CAR) and maximal volumetric voluntary contraction (MVC) of the quadriceps. The cryotherapy application time varied between 20 and 30. (1, 4, 6, 7, 25) CAR and MVC was measured before the application, immediately after, 30 minutes post, and 45 minutes post. In all cases CAR was higher in those who received cryotherapy. The greatest effects on CAR and MVC were observed between 30-45 minutes after a session of joint cooling providing a window of 30-45 minutes for strengthening exercises to be performed. Cryotherapy can be used clinically before therapeutic exercise to increase voluntary activation and potentially maximize
upon strength gains as a result of greater motor output. This is attributed to the increase in
the neural excitability of the tissues surrounding the involved joint following ice
application. (1, 5, 24)

2.3.2 Transcutaneous Electrical Nerve Stimulation in the Reduction of AMI

An overall increase in strength and voluntary quadriceps activation has also been
shown immediately following the use of TENS. (5) Many studies report an application
for 30 to 45 minutes. (7, 25) In studies that investigated length of application (7, 25), there
was no difference in effect whether the treatment time was 30-45 minutes. Research
shows that when TENS is used in combination with therapeutic and strengthening
exercises that there is an overall greater improvement in strength when compared to
groups who used strengthening exercises alone. However, disinhibitory effects only occur
while TENS is being applied. Cryotherapy and TENS are both disinhibit the quadriceps
following an artificial knee effusion. Cryotherapy allowed by showing an increase in
central activation ratio for to continue for up to 30 minutes after application. TENS had a
significant effect on AMI during the 30- 45 minute application, and by 30 minutes post
treatment the effects are greatly diminished. (25) It should be noted that most research
has been conducted on healthy, artificially effused knees. The joint is healthy in nature
and pain may not be a contributing factor to this model. (24) Pain is an important
indicator to joint dysfunction and can be a major contributing factor to AMI. (1, 5, 24)

Both cryotherapy and TENS have demonstrated to be useful tools in the reduction
of AMI. (6, 7, 25) Cryotherapy has immediate and lasting effects on AMI for a period of
30- 45 minutes after intervention. (5) TENS has immediate effects on AMI but the
disinhibitory characteristics are greatly diminished as the intervention is ceased.\(^{5, 25}\) The ability to be used in conjunction with therapeutic and strength exercise is one of the benefits of using TENS as a disinhibitory intervention.

### 2.4 Electromyographic Biofeedback

Electromyographic biofeedback (EMG-BF) is a useful rehabilitation tool for minimally invasive arthroscopic knee surgeries, patellofemoral pain syndrome, and knee osteoarthritis.\(^{5, 9, 13, 14, 17}\) EMG-BF is used in a clinical setting to help the patient gain voluntary neuromuscular control and muscle reeducation.\(^{8, 28}\) Biofeedback uses visual or audible cues to indicate electrical activity of the muscle. It is often encouraged to be used in conjunction with strengthening exercises because it increases compliance and motivation of the patient.\(^{14}\)

Current research suggests that when EMG biofeedback is supplemented with strengthening exercises, the benefits are greater than that of exercise alone.\(^{1, 4, 27}\) Patients given an EMG-BF intervention with exercise at two-weeks postoperative arthroscopic procedures demonstrated significantly greater extensor torque and quadriceps muscle fiber recruitment when compared to an exercise only group.\(^{14}\)

Kirnap and Calis evaluated the efficacy of EMG-BF on quadriceps strength after arthroscopic menisectomy.\(^{9}\) Range of motion, Lysholm scores, and peak EMG values of the vastus medialis, and vastus lateralis were evaluated pre-operatively as well as, 3 days, 2 weeks, and 6 weeks post-operation. There was no significant difference in knee flexion, Lysholm scores, and peak EMG at 3 days after surgery. There were significant increases in ROM, Lysholm scores, peak EMG, and overall strength of the vastus
medialis and vastus lateralis from 2 to 6 weeks post surgery when compared with the control group who only received traditional exercises. Overall when comparing the control group to the EMG-BF, group scores significantly favored the group who received EMG-BF(9).

When combined with exercise over an 8-week period EMG activity indicated a greater activation of vastus medialis and vastus lateralis increased in patients with patellofemoral pain syndrome who received the exercise treatment supplemented with EMG-BF.(5). When comparing baseline measures to the 8 week measures, the exercise group supplemented with EMG-BF demonstrated higher measures of activation of vastus lateralis and vastus medialis, thus. EMG-BF may be used increase activation of the vastus medialis and vastus lateralis muscles. Increase in activation was credited to the real time feedback, which allowed for integration of sensory and motor recruitment of muscles. (5)

2.4.1 EMG Biofeedback in Reduction of AMI

The current research on EMG-BF focuses on improving range of motion (9, 14), functional strength (8, 16), and activation of the muscles. (5, 12, 22) The effect of EMG-BF on corticomotor excitability has not yet been evaluated. This study aims to examine the potential benefits of EMG-BF in targeting AMI through this motor pathway and to determine if EMG-BF has the potential to be a beneficial clinical intervention.

2.5 Transcranial Magnetic Stimulation

Corticomotor excitability can be measured by performing transcranial magnetic stimulation (TMS) over the motor cortex. (29) When the stimulus is given a motor
Motor evoked potential is produced. Motor evoked potential can be interpreted and used as a measure of muscle excitability. (3, 29) It is suggested that after injury corticomotor excitability is affected. (3) TMS can also be used as a reliable measurement tool to assess the effects interventions have on corticomotor excitability.

Motor excitability is assessed by first finding active motor threshold (AMT); this is done by establishing an upper and lower threshold. The stimulator intensity lowered until there is no evidence of motor evoked potential (MEP). Once there is no MEP, the stimulator is increased gradually until MEP reappears. If there are consecutive trials that elicit responses lower than the desired MEP, this is established as the lower threshold. (3) The stimulator intensity is increased until consecutive trials elicit a value greater than the desired MEP, this is the upper threshold. After motor threshold is found, stimulator intensity can be increased by 5% or 10%, and responses recorded. The stimulus response (SR) curve can be established. SR is the relationship of the peak to peak values and the increase in stimulus. The SR can be compared bilaterally to as well as motor threshold to determine corticomotor excitability. (3)

2.6 Hoffman Reflex

The Hoffman reflex (H-reflex) is very similar to the spinal stretch reflex. The reflex can be electrically induced and the amplitude of the reflex is normalized to the amplitude of the muscle response. H-reflex bypasses the muscle spindles because of this can be used to evaluate the reflexive activity of the spinal cord. (4, 30) H-reflex is used as an estimate of alpha motor neuron (α-mn) excitability. H-reflex can be used as an
evaluation tool to assess the excitability of a motor neuron pool before and after an intervention.

An H-reflex can be induced by the use of electrical stimulation directed over a peripheral nerve. The H-reflex wave appears on EMG and as the stimulus is increased beyond the level needed to produce this, a new wave appears. This is known as the M-wave. Because this requires a higher level of stimulus a muscle contraction is elicited, but it bypasses the spinal cord so it is not considered to be a reflexive wave. At low levels of stimulus the H-reflex will appear on EMG along with the M-wave, however when the stimulus is further increased the H will reach its maximum and longer appear on EMG. The M-wave will continue to increase in amplitude as stimulus is continually being increased until M has reached its maximum. The maximal H-reflex represents the estimated number of motor neurons a person is thought to be able to activate. The amplitude of H-reflex is representative of motor neuron stimulation. A decrease in the amplitude after an injury is an indication of inhibition. M-wave maximum represents activation of the entire motor neuron pool. When the maximum is reached it is theorized that every motor neuron that is associated with the muscle is being activated. Because these are both representative of motor neuron recruitment, Hoffman reflex is an effective measurement tool.
Chapter 3

Methods

3.1 Experimental Design

This study was a crossover design where all participants served as their own control. Each participant received both conditions over two sessions that were separated by a one week wash out period. Order of the session and procedures were randomized using a random number generator.
Figure 3-1: Order of procedures for control, and intervention testing session.

Mmax = Maximal Muscle Response, MVIC= Maximal Voluntary Isometric Contraction, AMT= Active Motor Threshold, MEP= Motor Evoked Potential, EMG=BF= Electroyographic Biofeedback

3.2 Participants

Twelve healthy participants volunteered for this study (Table 1). Participants had no previous history of lower extremity injury within the last 6 months. All participants read and signed a university approved IRB informed consent form. In order to be considered for participation in this study the subjects met specific inclusion and exclusion criteria. For participants to be included in the study, the outcome measures we were looking to obtain must have been able to be elicited during each session. At anytime if these measures were not able to be obtained the participant was excluded. Participants
were not included if they were involved in an ongoing lower extremity strengthening or exercise program.

Participants were excluded from the study if they had a history of lower extremity fracture or orthopedic surgery in either limb in the last 6 months, history of lower extremity ligamentous injury resulting in pain, swelling, or loss of time from daily or sports related activities. Participants were also excluded from the study if they had a history of heart condition, history of seizure, or concussion within the past 6 months. Exclusion also included those with a previous history of diagnosed cancer over stimulation points such as the brain, or any participants that were currently taking any medications which may alter neural function such as antidepressants or muscle relaxers.

3.3 Instrumentation

Corticomotor Excitability

The motor evoked potentials were elicited using the Magstim Rapid (Magstim Company, Wales, UK) via a double cone coil (Magstim Company, Wales, UK). The magnetic stimulation did not exceed 1.4 Tesla. All motor evoked potentials were measured in the peripheral muscles using disposable disk-shaped 10 mm pre-gelled Ag/AgCl electrodes (BIOPAC Systems, Inc) used to acquire EMG signals. Acqknowledge BIOPAC Software (BIOPAC Version 3.7.3, BIOPAC Systems, Inc.) was used to visualize the signals.
EMG- Biofeedback

A handheld biofeedback unit; Myotrac Infiniti (Thought Technology Ltd, Quebec, Canada) was used during the measurement of motor evoked potentials at active motor threshold while performing MVIC.

Maximal Muscle Response- $M_{\text{max}}$

Maximal M-wave measurements were collected with surface electromyography (MP100C BIOPAC Systems, Inc Goleta, CA). Analog to digital signal conversion was processed with a 16 bit converter (MP150, BIOPAC Systems Inc). The Acqknowledge BIOPAC Software (BIOPAC Version 3.7.3, BIOPAC Systems, Inc.) was used to visualize the signals as well as manipulate the stimuli. Signals were sampled at 1024 Hz and electromyography (EMG) amplification were set at a gain of 1000 (EMG100C BIOPAC Systems, Inc.). The common mode rejection ratio of our EMG amplifier was 100 dB and the input impedance was 2MOhms. The disk-shaped electrodes used to acquire signals are disposable, 10 mm pre-gelled Ag/AgCl (BIOPAC Systems, Inc). The electrodes were positioned 1.75 mm apart over the vastus lateralis. Stimulus was be provided with the BIOPAC stimulator module (STIM100A, BIOPAC Systems, Inc.), a 200 volt maximum stimulus isolation adaptor (STIMSOC BIOPAC Systems, Inc), a 2 mm shield disk electrode, (EL254S)
3.4 Procedures

Maximal Voluntary Isometric Contraction

Maximal voluntary isometric contractions were performed in order to establish normalized intensities for corticomotor excitability testing. Participants were seated in the Biodex System 2 dynamometer (Biodex Medical Systems, Shirley, NY) to measure maximal voluntary force to establish a baseline MVIC for each testing session. Prior to each exercise session skin was shaved and debrided over the belly bulk of the vastus lateralis. Surface electrodes were positioned on the vastus lateralis. Participants were seated in the dynamometer positioned in 85° of trunk flexion and 90° of knee flexion. Straps were placed around the mid thigh and around the middle of the calf. Straps were also placed over the shoulder and across torso of the participants to ensure proper positioning. The participant performed 2-3 warm up trials at submaximal contraction. After the warm up trials the participant performed 5 maximal isometric contractions of the quadriceps. The participants were given a 60 second rest period between each trial to prevent fatigue. Torque was also monitored during MEP testing sessions using Aqknowledge software. These values were recorded and averaged.

Corticomotor Excitability

The collection of motor evoked potentials have been reported in a variety of subject populations (anterior cruciate ligament injuries, knee pain, healthy participants) and has been reported reliable in healthy subjects (intraclass correlation coefficient [ICC3,1=0.87]).(31) Participants were seated in the Biodex System 2 dynamometer at
85° of trunk flexion and 90° of knee flexion. Participants wore lycra swim cap which allows the investigator to optimally position the magnetic coil and make marks if necessary. Disposable earplugs were given to each subject to protect their ears, because of the noise during stimulation of the motor cortex.

Participants remained seated in the Biodex System 2 dynamometer as previously described. We then took 5% of the average torque from the MVIC’s and entered that value into the Biodex software, to allow for a torque to be continually monitored during active motor threshold testing. To elicit an MEP on the contralateral limb, a double cone coil (Magstim Company, Wales, UK) will be positioned over the vertex of the cranium and Magstim rapid (Magstim Company, Wales, UK) was used to produce a maximum magnetic stimulus of 1.4 Tesla. The coil was moved until stimulus is directed over the motor cortex until a MEP response was found and marked on the swim cap. Motor threshold refers to the lowest TMS intensity necessary to evoke a MEP in the targeted muscle. Motor threshold is recorded lowest intensity required to elicit a MEP of 0.1. Threshold was recorded when 5 of 10 trials are >0.1μV and 6 of 10 trials are < 0.1μV. Once Active Motor Threshold was found 5 stimuli at AMT were given and recorded.

Corticomotor Excitability MVIC

All stimuli were given at AMT for this testing procedure. The monitor that was placed in front of them during the initial MVIC session was then removed. The torque input from the Biodex System 2 P Dynamometer was then connected to the BIOPAC MP150 analog to digital signal converter. This allowed for the torque output from the participant to be visualized using BIOPAC Aqknowledge software. This ensured that the
investigator elicited a MEP only during a maximal contraction of the vastus lateralis. Practice trials were given so the participant could become familiar with the procedure. The participant was then asked to perform an MVIC of the quadriceps. As they extended their knee, they received verbal encouragement to reach their maximal effort. When maximal effort plateaued a stimulus was given and the MEP peak-to-peak amplitude was recorded. This was performed for 5 consecutive trials with 60 seconds of rest between each MVIC.

**Maximum Muscle Response- $M_{\text{max}}$**

Maximum muscle response was recorded in order to normalize all motor evoked potentials for each participant. Participants laid supine on a padded treatment plinth or stand with their arms comfortably placed at their side with their head in a neutral position. The head of each participant rested comfortably on a pillow and their knees slightly flexed. The hair over the collection sites was shaved and the skin over the recording electrode site was debrided and cleaned with alcohol. Two 10mm, pre-gelled Ag-AgCl (EL503, BIOPAC Systems Inc) surface electromyography electrodes were position 2cm apart over the vastus laterlis. Electromyographical signals were band-pass filtered from 10 to 50 Hz and collected at 1024HZ with a common-mode-rejection ratio of 110 dB. A 2mm shielded disc stimulating electrode (EL2524S, BIOPAC Systems Inc) was positioned over the femoral nerve and secured with tape and a self adhesive electrode was positioned over the hamstring and used as a dispersive electrode. A 1ms square wave stimulus was produced with a BIOPAC stimulator module (STM100A,
BIOPAC Systems, Inc) and a 200 volt maximum stimulus adaptor (STMISOC, BIOPAC Systems Inc) and delivered to the femoral nerve.

During testing participants were instructed to maintain a constant head, eye and hand position by focusing on a circle on the ceiling. The stimulus was increased until a maximal muscle response is elicited, in which 3 maximal muscle responses were then elicited and recorded. Electrodes were positioned on the vastus lateralis muscles to collect the signal elicited by the electrical stimulation. The M-max was used to normalize the MEP collected during corticomotor excitability.

3.4.1 Intervention

Subjects were supplemented with a Myotrac Infiniti hand held biofeedback unit during corticomotor excitability testing. Electrodes for the Myotrac biofeedback unit were placed over the vastus lateralis. Leads will be carefully monitored as they are next to the leads that are necessary to be used for the measurement of AMT. The participant performed 2-3 warm up trials or until the investigator felt comfortable that they understood the procedure. This was done in order to become familiar with using the Myotrac handheld biofeedback unit during AMT testing. The participant was asked to perform three MVIC’s and their peak EMG values were averaged. The Myotrac unit was set at 110 % of their peak EMG that was recorded. The procedure for AMT testing remained the same as previously mentioned. The biofeedback unit had an indicator bar monitoring their peak EMG during each of the 5 trials. They were asked to try and reach their maximum value during each posttest. While they were performing the MVIC’s, a
stimulus was given at their AMT. MEP peak to peak values were recorded for each of the 5 trials. Torque production was monitored in the same manner that was previously discussed. This allowed the investigator to ensure consistency between all 5 of the MVIC trials.

3.5 Statistical Analysis

The five peak to peak MEP values from the pre-intervention testing session were averaged. The five peak to peak MEP values from the EMG-BF and Control posttests were averaged. Averaged values were used to create change scores between the pre-intervention and EMG-BF and Control MVIC intervention sessions.

Dependent t-tests were used to assess the differences between changes in MEP amplitude at AMT in control and EMG- biofeedback intervention groups. Results were represented as percentage of change from baseline scores. Percent change scores were used to determine if corticomotor excitability differences existed between EMG-BF and Control conditions. Standardized Cohen’s $d$ effect sizes and 95% confidence intervals were used to determine the magnitude of difference between conditions. Dependent t-tests were also used to determine the differences in mean torque measures between intervention testing sessions. An a priori alpha level was set at $p<0.05$ during statistical analysis.
Chapter 4

Results

4.1 Results

Demographic data for all participants are shown in Table 4.1.1. The percent change scores for MEP amplitude at AMT was significantly greater in the biofeedback condition compared to the control ($t_{11} = -2.308$, $p = .041$) (Table 4.1.1). Large effect sizes were found for both the control ($d = 3.92$, 95% CI = 2.45-5.12), and biofeedback condition, ($d = 2.77$, 95% CI =1.58- 3.78). A moderate effect size was found between the two conditions, ($d = 0.62$, 95% CI= -0.22- 1.42). There was also an overall increase in MEP amplitude between the baseline, and the intervention sessions for both the control MVIC session and the MVIC with biofeedback session. There was no statistical difference in the torque measures between the control, and the biofeedback intervention sessions ($t_{11} = -2.205$, $p = .068$) (Table 4.1.3).
Table 4.1.1: Participant Demographic Information

<table>
<thead>
<tr>
<th>Number of Participants</th>
<th>n = 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>6 Male</td>
</tr>
<tr>
<td></td>
<td>6 Female</td>
</tr>
<tr>
<td>Age, yr</td>
<td>21.41 ± 4.41</td>
</tr>
<tr>
<td>Height, cm</td>
<td>172.82 ± 11.23</td>
</tr>
<tr>
<td>Mass, kg</td>
<td>72.58 ± 15.77</td>
</tr>
</tbody>
</table>

Table 4.1.2: Significance and Effect Sizes with respective 95% Confidence Intervals for the Percent Change MEP amplitude from baseline to intervention test

<table>
<thead>
<tr>
<th>Control Condition</th>
<th>EMG- Biofeedback Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=12</td>
<td>n=12</td>
</tr>
<tr>
<td>Baseline</td>
<td>MVIC</td>
</tr>
<tr>
<td>MEP: MMAX</td>
<td>0.010 ± .003</td>
</tr>
<tr>
<td>% Change</td>
<td>1522.204 ± 354.667</td>
</tr>
<tr>
<td>Significance</td>
<td></td>
</tr>
<tr>
<td>Effect Size 95% CI</td>
<td>3.92</td>
</tr>
<tr>
<td></td>
<td>Lower 2.45</td>
</tr>
</tbody>
</table>

*EMG-BF= Electromyographic Biofeedback, MEP= Motor Evoked Potential, M_MAX= Maximum Muscle Response, MVIC= Maximal Voluntary Isometric Contraction*
Figure 4-1: Motor Evoked Potential Change Scores for Control and EMG-BF Conditions. Significant increase in motor evoked potential amplitude for the EMG-BG conditions. P=0.041

Table 4.1.3: Average Torque During MVIC for Control and EMG-BF Condition

<table>
<thead>
<tr>
<th></th>
<th>Control Condition</th>
<th>EMG-BF Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=12</td>
<td>n=12</td>
<td></td>
</tr>
<tr>
<td>Avg. Torque, V</td>
<td>3.354 ± 1.644 V</td>
<td>3.571 ± 1.790 V</td>
</tr>
<tr>
<td>Significance</td>
<td>p=.068</td>
<td></td>
</tr>
</tbody>
</table>

* Indicates Significance

V= Volts
Figure 4-2: Average Torque Values During MVIC for Control and EMG-BF Condition. No significant increase in average torque during MVIC for the control and EMG-BF conditions. P=0.068

Figure 4-3: Effect Sizes with 95% Confidence Intervals for Control and EMG-BF Conditions. Large effect for control condition, $d=3.92$. Large Effect for EMG-BF, $d=2.77$. Moderate effect between conditions, $d=0.62$. 
Chapter 5

Discussion

The purpose of this study was to determine the acute effects during a single bout of EMG- BF on corticomotor excitability and MVIC in healthy individuals, compared to no biofeedback. This study provides evidence to suggest that corticomotor excitability is increased immediately during a single bout of EMG- BF when compared to a control intervention. The change scores calculated for each condition showed significantly greater increases in MEP amplitudes with the use of EMG- BF during an MVIC, compared to the control condition with no biofeedback. During corticomotor excitability testing, the MEP produced is interpreted as a measure of muscle excitability. (3, 29) An increase in MEP amplitude can be interpreted as an overall increase in excitability of the motor cortex and motor portions of the descending spinal tract.

AMI is a result of altered neural function, which contributes to deficits in voluntary activation and strength in patients with a knee injury. (1, 7, 15, 19, 24) It is hypothesized that altered neural function originates from either a deficit in the spinal reflexive pathway or the corticomotor pathway. Clinical interventions such as cryotherapy (5, 6), and TENS (7) have been used in an effort to address these
neuromuscular deficits after joint injury with varying degrees of success. These modalities have shown the capability of altering spinal excitability. However, the effects of these modalities on the corticomotor pathway remain unknown. To our knowledge, there are limited modalities that have been identified to alter corticomotor excitability. EMG-BF has been used for a variety of knee pathologies. (9, 10, 12) EMG-BF has been shown to increase voluntary strength of the quadriceps muscle group. There is little evidence that demonstrates the effectiveness of EMG-BF in increasing corticomotor excitability, however there is a correlation between corticomotor changes in strength and activation measures. (3) Identifying modalities that are capable of targeting AMI that has cortical origins may allow for increased gains in strength and activation of the affected musculature.

Previous literature has demonstrated that using electromyographic biofeedback can increase activation and strength of the affected musculature. (9, 32, 33) Ng et al. (33) found that patients with patellofemoral pain syndrome that participated in an 8-week therapeutic exercise program increased vastus lateralis and vastus medialis activation ratios. Researchers only observed a significant increase in the group of participants that had been supplemented with EMG-BF when compared to a control group that participated in an 8-week therapeutic exercise program (33). Ekblom (32) studied the acute effects of electromyographic biofeedback on activation levels of the vastus lateralis and vastus medialis. Ekblom broke down the movement into pre-activation, initial movement, and late movement phase. EMG-BF was shown to have a greater influence on the activation of the VMO and VL in the pre-activation and initial movement phases. An increase in activation of these muscles resulted in higher peak EMG values for those who
were supplemented with biofeedback. The biofeedback group also demonstrated higher torque values in the concentric pre-activation and initial movement phase. The increases in activation and strength measurements showed that EMG-BF is a viable option that could be used clinically to increase the activation ratio in those patients with patellofemoral pain syndrome. Draper (16) noted that when EMG-BF is used in conjunction with a traditional 12-week therapeutic exercise program following ACL reconstruction patients achieved a greater increase in peak isometric torque measurements than compared to a control group at each of the three testing angles (50° and 0°). Individuals that were supplemented with EMG-BF following ACL reconstruction achieved full extension of the joint, on average, 15 days quicker than those who did not use biofeedback. Evidence supports the use of EMG-BF in conjunction with a traditional therapeutic exercise program in order to improve overall strength of the VMO and VL (32, 34). In both studies the exercise group demonstrated strength increases, however the exercise group that was supplemented with EMG-BF showed significantly greater increase in strength over the course of the program. During an eccentric movement pattern EMG-BF was associated with overall higher torque values throughout all three phases of the movement (32). When comparing eccentric and concentric strength improvements, eccentric strength patterns were more easily influenced by the supplementation of biofeedback. EMG-BF showed a greater influence on eccentric contractions because they require a lower voluntary activation level (32). EMG-BF seems to have greater effects on sedentary individuals rather than trained people (16, 32).
EMG- BF should be considered clinically following knee injury to increase strength and overall activation of the musculature surrounding the joint following injury. Biofeedback provides real time visual or auditory feedback to indicate the electrical activity of a muscle. Although the mechanism of EMG-BF is relatively unknown, it has demonstrated a positive effect on the increases in strength (10, 12, 16), activation (5), and muscle reeducation. (14, 17). The positive results associated with biofeedback could stem from the involvement of the patient during the treatment. The patient constantly receives information about the quality of contraction of their knee musculature. During muscular re-education the patient must re-learn the correct motor recruitment in order to regain proper activation. (12, 16) Without real time biofeedback they lack reassurance that they are achieving an optimal motor response. Because EMG-BF provides the patient with this visual evidence they are able to achieve greater muscle recruitment and are able to relearn motor patterns at a considerably quicker rate. EMG-BF is also thought to be effective because it can be used to increase the motivation of the patient. By providing the patient with information they are able to be more involved and tend to have a greater interest in their own treatment. A study conducted by Hald and Bottjen (35) showed that participants were able to produce significantly greater peak torque when provided with a form of visual feedback when compared to those who did not receive real time feedback on their performance. It has been demonstrated that visual feedback may elicit greater performance and has been considered to be a motivational modality. (12, 16, 17)

Biofeedback can constantly provide the patient with a new goal each time it is used. This study was aimed at investigating the mechanisms in which EMG-BF effects corticomotor excitability. During this study participants were provided with EMG-BF
and asked to produce a MVIC of the quadriceps. The increase in corticomotor excitability could be attributed to motivation provided to them by the use of the biofeedback unit. Even though torque measures remained consistent throughout both the control and intervention sessions there was a greater increase in MEP amplitude during the EMG-BF condition when compared to the control session. The increase in MEP amplitude when using EMG-BF could due to increased awareness of the task and, therefore, increased corticomotor drive in effort to contract the quadriceps. The use of EMG-BF could exhibit neural increases due to an increase in the firing rate and the recruitment of motor units during this task. An increase in motor units usually results in an increase in torque production; however during this study an increase in torque was not shown. Therefore the increase in corticomotor excitability could be due to the supplementation of EMG-BF during the MVIC.

This study provides evidence that electromyographic biofeedback can acutely increase corticomotor excitability. However the results can only be generalized to healthy individuals. Healthy individuals were selected for this study because there is no previous literature that demonstrates the ability of EMG-BF to alter corticomotor excitability. Other limitations include a limited number of participants. A greater number of participants could further support the claims that EMG-BF can be used to increase corticomotor excitability. Participants were supplemented with EMG-BF during one testing session. EMG-BF has only been shown to have an acute effect on corticomotor excitability. It remains unknown whether there will be any lasting effects following the use of this intervention. Physical activity was not documented between each testing
session so it is unclear whether an individual’s exercise routine had an effect on the corticomotor measurements.

The results of this study demonstrate that corticomotor excitability can be increased during a single bout of EMG-BF, however further evidence is needed to indicate effectiveness of this modality and its ability to increase corticomotor excitability over multiple sessions. Previous research on cryotherapy has demonstrated lasting effects for up to 45 minutes after application. (7) Further investigation is also needed to show if EMG-BF has a long term effects on corticomotor excitability. Future research should focus on the use of EMG-BF in conjunction with traditional therapeutic exercise program to discover if there is a greater magnitude of change in cortical excitability as well as an increase in overall strength when the two are used in unison. Further research is needed to discover if there is a relationship between an increase in corticomotor excitability and the ability to perform functional tasks such as a single leg hop or a vertical jump. EMG-BF has been shown to increase strength and activation in a variety of patient populations. However, it is unknown if corticomotor excitability can be altered in different patient populations. There is evidence that shows the ability of EMG-BF to increase activation of the quadriceps following acute joint injury, therefore researchers could also focus on this modality and if there is a correlation between the increase in activation and the increase in cortical excitability.

The results from this study suggest that a single bout of EMG-BF can be used to alter corticomotor excitability in healthy individuals. This is the first study to demonstrate
that EMG-BF can be used to immediately increase in corticomotor excitability in a healthy population.
References


Appendix A

University of Toledo IRB Consent Form
ADULT RESEARCH SUBJECT INFORMATION AND CONSENT FORM
THE IMMEDIATE EFFECT OF ELECTROMYOGRAPHIC BIOFEEDBACK ON QUADRICEPS CORTICOMOTOR EXCITABILITY

Principal Investigator: Brian Pietrosimone PhD ATC
Other Staff (identified by role): Michelle McLeod (Co-Investigator) David Florea (Co-Investigator)
Contact Phone number(s): (419) 530-4467

What you should know about this research study:

- We give you this consent/authorization form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will be communicated to you verbally by the research staff as well.
- Routine clinical care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- We cannot promise that this research will benefit you. Just like routine care, this research can have side effects that can be serious or minor.
- You have the right to refuse to take part in this research, or agree to take part now and change your mind later.
- If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.
- Please review this form carefully. Ask any questions before you make a decision about whether or not you want to take part in this research. If you decide to take part in this research, you may ask any additional questions at any time.
- Your participation in this research is voluntary.

PURPOSE (WHY THIS RESEARCH IS BEING DONE)
You are being asked to take part in a research study looking at the nerve function of your thigh muscles.

The purpose of the study is to determine if people with a previous knee injury have different nerve excitability between legs and compared to individuals without a history of knee injury, and if exercise training will alter this nerve function. You were selected as someone who may want to take part in this study because you have had an anterior cruciate ligament reconstruction to one knee, or no history of lower extremity injury. There will be approximately 70 people participating in this study at the University of Toledo.
DESCRIPTION OF THE RESEARCH PROCEDURES AND DURATION OF YOUR INVOLVEMENT

If you decide to take part in this study, you will be asked to report to the Joint Injury and Muscle Activation (JIMA) Laboratory in the Health Science and Human Services building (Room 1409). You will be asked to fill out Knee Injury/Ankle Injury Questionnaires about how your knee/ankle feels during different activities. We will then test the neural function of both of your legs using 3 different methods. These methods include muscle activation testing, Reflex Testing, and Motor Cortex Testing. Testing sessions (2 total) will be completed in approximately 1 hour each. Each session will consist of either an experimental or control intervention that will be determined at random.

Ankle and Knee Injury Questionnaires
You will be asked to provide us information regarding your previous history of your joint injury, current and past level of activity and how your joint injury currently affects you during different activities.

Muscle Activation/Strength Testing
You will be asked to stand near the testing chair and two electrodes treated with gel will be place on your thigh. One of the electrodes will be placed above your knee and the other will be given to you to place below your hips so that it lies flat when you are sitting. The electrodes will be held in place with an elastic bandage. These electrodes will be used to deliver a brief, mild electrical stimulus to your thigh muscles. The electricity will be approximately a half a second in duration and will contract your thigh muscle for that half second and relax.

You will be asked to sit in a chair that resembles a car seat. You will have a seat belt applied so that you do not move as you are contracting your leg muscles as hard as you can. You will then be asked to extend your leg as hard as you can and hold it for five seconds. While you are extending out the electrical stimulus will be delivered to your thigh. This stimulus feels similar to a static electric shock that you could get from walking across a carpet in a dry room and then touching a doorknob, although the voltage is lower. You will be asked to perform this at least three times at 5 different periods throughout each session at 3 different positions on both legs. You will be allowed up to 1 minute of rest between each repetition.

Reflex Testing
This testing provides an estimate of how well nerves in the lower leg are functioning. You will be instructed to stand on your dominant leg or lie on a table. You will have sticky electrodes placed on your lower legs and thigh. These electrodes are called EMG electrodes which stand for Electromyography which is a recording of the electrical (reflex) activity in skeletal muscle. The sites of the EMG electrodes will be shaved and cleaned with alcohol. An electrode that provides a stimulus will be taped behind your knee and in the front of your hip. Several reflex measurements will be taken while you are balancing or lying down.
- These measurements include a 1-millisecond stimulus.
- The intensity of this stimulus will vary depending on the reflex being elicited.
- The stimuli in this study feel similar to static electricity felt as you touch a door knob after walking across a carpet.
- A series of measurements will be taken on both legs

Motor Cortex Testing
This testing provides us important information regarding how your brain is sending messages to muscles in your legs. You will be asked to lie on a table with your hands at your side. We will position a coil over your head and adjust the position of the coil until it is in the correct spot. We will ask you to wear a bathing cap and ear plugs. A brief magnetic stimulus will then be produced which will sound like a "click." You will not have and associated pain or discomfort in your head, but rather may feel a brief
muscle contraction in the muscles of your leg or thigh. You will be asked to flex certain leg muscles at a small to moderate intensity while we provide a series of brief magnetic stimuli to your head.

**Biofeedback or Control**
You will be asked to come to 2 test sessions in the laboratory that will take approximately 1 hour each. During the experimental test session you will be asked to perform a maximal voluntary contraction of the quadriceps with the use of a biofeedback unit. This device will provide visual biofeedback regarding how much you are able to voluntarily contract your quadriceps muscle. During the control session you will be asked to perform the same maximal contraction without the use of a visual feedback device, which we have termed the control session. You will be supervised during this treatment by a certified athletic trainer and/or student athletic trainers.

**RISKS AND DISCOMFORTS YOU MAY EXPERIENCE IF YOU TAKE PART IN THIS RESEARCH**

**Likely Risks**
- Mild discomfort for a very brief period during the electrical stimulation.
- Mild transient muscle soreness from exercise testing or muscle activation testing.

**Less Likely Risks**
- Mild, transient skin irritation from the sticky electrodes.

**Very Unlikely Risks**
- Mild, transient headache following magnetic stimulation
- In people with a history of seizures there is a slight possibility of causing a seizure with the magnetic stimulation; therefore you must tell us prior to testing if you have ever had a seizure so we can exclude you from the study.

**RISKS TO UNBORN CHILDREN**
It is unknown how the electrical stimulation used in this study would affect an unborn fetus; therefore, if you are pregnant you will not be allowed to participate in this study.

**POSSIBLE BENEFIT TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH**
We cannot and do not guarantee or promise that you will receive any benefits from this research.

**COST TO YOU FOR TAKING PART IN THIS STUDY**
You are not directly responsible for making any type of payment to take part in this study. However, you are responsible for providing the means of transportation to the Joint Injury and Muscle Activation Laboratory. You will not be compensated for gas for travel or any other expenses to participate in this study.

**PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH**
There will be no compensation for participation in this research study.

**PAYMENT OR OTHER COMPENSATION TO THE RESEARCH SITE**
The University of Toledo is receiving money or other benefits from the sponsor of this research as reimbursement for conducting the research.
ALTERNATIVE(S) TO TAKING PART IN THIS RESEARCH
The only alternative is not to participate in this study.

CONFIDENTIALITY
The researchers will make every effort to prevent anyone who is not on the research team from knowing
that you provided this information, or what that information is. The consent forms with signatures will be
kept separate from the information we collect, which will not include names and which will be presented
to others only when combined with other responses. Although we will make every effort to protect your
confidentiality, there is a low risk that this might be breached.

IN THE EVENT OF A RESEARCH-RELATED INJURY
In the event of injury resulting from you taking part in this study, treatment can be obtained at a health
care facility of your choice. You should understand that the costs of such treatment will be your
responsibility. Financial compensation is not available through The University of Toledo or The
University of Toledo Medical Center. By signing this form you are not giving up any of the legal rights of
your son/daughter/legal charge as a research subject. In the event of an injury, contact Brian
Pietrosimone, PhD, ATC (419) 530-4487

VOLUNTARY PARTICIPATION
Taking part in this study is voluntary. You may refuse to participate or discontinue participation at any
time without penalty or a loss of benefits to which you are otherwise entitled. If you decide not to
participate or to discontinue participation, your decision will not affect your future relations with the
University of Toledo or The University of Toledo Medical Center.

NEW FINDINGS
You will be notified of new information that might change your decision to be in this study if any becomes
available.

ADDITIONAL ELEMENTS
There is no other additional information for this study.

Continued on Next Page
OFFER TO ANSWER QUESTIONS
Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over. If you have questions regarding the research at any time before, during or after the study, you may contact: Dr. Brian Pietrosimone- (419) 530-4467

If you have questions beyond those answered by the research team or your rights as a research subject or research-related injuries, please feel free to contact the Chairperson of the University of Toledo Biomedical Institutional Review Board at 419-383-5796.

SIGNATURE SECTION (Please read carefully)

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE INFORMATION PROVIDED ABOVE, YOU HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND YOU HAVE DECIDED TO TAKE PART IN THIS RESEARCH.

BY SIGNING THIS DOCUMENT YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION AS DESCRIBED IN THIS FORM.

The date you sign this document to enroll in this study, that is, today’s date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. These dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study. Each page of this Consent/Authorization Form is stamped to indicate the form’s validity as approved by the UT Biomedical Institutional Review Board (IRB).

<table>
<thead>
<tr>
<th>Name of Subject (please print)</th>
<th>Signature of Subject or Person Authorized to Consent</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relationship to the Subject (Healthcare Power of Attorney authority or Legal Guardian)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of Person Obtaining Consent (please print)</td>
<td>Signature of Person Obtaining Consent</td>
<td>Date</td>
</tr>
<tr>
<td>Name of Witness to Consent Process (when required by ICH Guidelines) (please print)</td>
<td>Signature of Witness to Consent Process (when required by ICH Guidelines)</td>
<td>Date</td>
</tr>
</tbody>
</table>

YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.
Appendix B

Knee Injury History Questionnaire
Please Circle (Yes or No) regarding your situation.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Have you had an injury to either leg that has altered you function in the past 6 months?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Have you had a surgery to either leg (knee, ankle, hip) in the past six months (other than meniscectomy)?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Do you have any knee ligaments that have not been reconstructed?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Do you have any nerve injuries in your legs or lower back?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Do you have any known muscular abnormalities?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Do you have a heart condition that would stop you from exercising?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Have you ever been diagnosed with cancer over your knee or thigh?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Do you currently have an infection over your thigh or in your knee?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Do you know of a hypersensitivity to electrical stimulation?</td>
</tr>
</tbody>
</table>

1. **Have you ever had a knee injury?**
   
   When (month / year): __________________________
   
   Explain: __________________________________________________________

2. **Have you ever had a knee Surgery?**
   
   When (month / year): __________________________
   
   Explain: __________________________________________________________

   If ACL Reconstruction, What graft type? ____________________________

3. **Did you participate in physical therapy or therapeutic exercise?**
   
   When did you start (month / year): __________________________
   
   For How Long: __________________________

4. **Have you ever had an injury/surgery to you ankle, hip or lower back?**
   
   When (month/year): __________________________
   
   Explain: __________________________________________________________

---

APPROVED BY  
UNIVERSITY OF TOLEDO IRB